

Serial No. 09/577,264
Docket No. 0002.12

REMARKS

This is a full and timely response to the outstanding final Office Action mailed August 29, 2007. Reconsideration of the application and allowance of presently pending claims as amended, are respectfully requested.

A. Present Status of Patent Application

Upon entry of the amendments in this response, claims 56-57 and 60-68 remain pending in the present application. By this Amendment, independent claims 56 and 66 are directly amended; and claims 57, 60-65, and 67-68 indirectly amended as they depend from amended independent claim 56 or 66. Claims 60 and 66 were also amended.

It is believed that the foregoing amendments and additions add no new matter to the present application and no estoppels are intended thereby, and are made to place the claims in condition for allowance or appeal.

B. Response To Rejections

1. Rejections under 35 U.S.C. §112

Claims 56, 57, 60 and 63-67 were rejected under 35 U.S.C. §112, second paragraph, as allegedly failing to particularly point out and distinctly claim the invention, in view of the recitation of treatment of a patient showing no signs of osteoporosis.

In response, applicant has amended Independent claims 56 and 66 to recite that the method is one of treatment of osteoporosis.

Claims 56, 57, 60 and 63-67 were rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite. In response applicant has amended claim 66 to recite that the composition is a powder, and claim 56 to recite that the powder comprises the specified particle size range. As such, claims 56, 57, 60 and 63-67 are definite. Claim 65

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was objected to as allegedly an inappropriate dependent form. This claim has been amended to clarify the scope thereof.

It is to be noted that enablement is found even if a reasonable amount of routine experimentation is required. *Enzo Biochem Inc v Calgene Inc*, 52 USPQ 2d 1129 (Fed Cir 1999.) Moreover, the *In re Wand* factors are not to be construed as an absolute requirement; not all of the factors need be reviewed when determining whether a disclosure is enabling. *Id.*

While applicant contends that even the un-amended claims are clear and satisfy 35 U.S.C. §112, the amendments further clarify the claimed method as one of treating osteoporosis by "administering by inhalation" the described formulation. Thus the treatment is properly claimed as the administration of the formulation, to any patient in need of such treatment. Such a claim is absolutely definite and certain.

2. Rejection under 35 U.S.C. §103

As reiterated by the Supreme Court in *KSR International Co. v. Teleflex Inc.*, S. Ct. 1727 (2007); 82 USPQ2d 1385, 1397 (2007), the factors stated in *Graham v. John Deere*, 383, U.S. 1, 148 USPQ 459 (1966) still control an obviousness inquiry. That is to say, the considerations which must be followed in an inquiry directed to the obviousness or non-obviousness of an invention are as follows:

- i. The claimed invention must be considered as a whole;
- ii. The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; and
- iii. The references must be viewed without the benefit of hindsight afforded by the claimed invention or accompanying specification.

In conducting the above analysis, one must consider the level of ordinary skill in the art at the time of the invention, as well as whether there exists a reasonable expectation of success.

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WANG in view of NEER

Claims 56, 57 60, 63, 64, 65 and 67 were rejected under 35 U.S.C. §103 as allegedly unpatentable over U.S. Patent No. 5,011,678 to Wang et al. in view of U.S. Patent No. 4,698,328 to Neer et al.

In response, applicant reiterates the distinction previously advanced, that neither Wang nor Neer teach or suggest the claimed powder composition as claimed, **and wherein** the composition is delivered by inhalation to the lungs of the patient. In particular Wang **requires** a composition comprising an amphiphilic steroid:

The invention is based on applicants' **surprising discovery** that the application to mucosal surfaces of certain amphiphilic steroids described by Carey et al., supra., in the form of non-aqueous, fluorocarbon- or hydrocarbon-based aerosol suspensions is not accompanied by any significant irritation of the type experienced by many subjects upon administration of the corresponding aqueous-based delivery systems
[emphasis added]

Column 3, lines 9-17, and:

In accordance with the present invention, there is provided a composition for the administration of a pharmaceutically active substance comprising:
(a) a medically effective amount of a pharmaceutically active substance;
(b) a biocompatible, amphiphilic steroid of the formula ##STR1##....

Column 3, lines 22-27.

The record is thus clear that the invention is premised upon the use of such steroids. With regard to the second quote, is to be noted that Wang does not qualify this statement in any way; rather the "present invention" is a composition "comprising... a biocompatible, amphiphilic steroid" as depicted and described.

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In the face of such written record, applicant disagrees with the Examiner's contention that the steroids of Wang are not essential. There has been no showing of any such teaching in Wang; to the contrary, every example (I through V) uses STDHF. In particular, Example V – a preparation for human parathyroid hormone, requires STDHF. According to MPEP 2143.01 and 2144.03, the PTO must support an obvious rejection by appropriate facts. See *In re Wagner et al*, 152 USPQ 552, 560 (CCPA 1967), and MPEP 716.02. The Office has not met its burden, and applicant's "consisting essentially of" claim form thus patentably distinguishes.

Finally, with regard to the method limitations *per se*, Wang discloses a serum profile only in respect of insulin (see Fig 2). It is well understood that pharmacokinetics of different actives can differ greatly, even if delivered in substantially the same way. While the inherent uncertainty of the biological arts does not itself render a result unobvious, there must be a reasonable expectation of success to support an obviousness rejection. With regard to a the pulsatile profile limitation, applicant submits that the insulin curve of Wang does not teach or suggest anything with regard to the claimed N-terminal fragment of parathyroid hormone, and the Examiner has proffered no evidence to the contrary. Thus applicant contends that Wang does not teach or suggest applicant's method as claimed.

Neer fails to cure the deficiencies of Wang. Neer suggests neither administering by inhalation nor a pharmaceutical composition including an aerosol propellant. Additionally, Neer is devoid of any teaching of the claimed method wherein a pulsatile serum concentration results.

In view of the above, Applicant respectfully requests that this ground of rejection be withdrawn.

WANG in view of MORITA

Claims 56-57, 60, 63-65 and 67 were rejected under 35 U.S.C. §103 as allegedly unpatentable over Wang in view of U.S. Patent No. 4,656,250 to Morita et al.

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Morita is limited to disclosing a PTH peptide, potentially useful for treating PTH deficiency conditions. Morita neither teaches nor suggests a formulation for administration by inhalation, nor administering by inhalation, nor a pharmaceutical composition including an aerosol propellant, nor a method of delivery resulting in a pulsatile serum profile.

Moreover, the same arguments made above in regard to Wang are similarly applicable here, i.e. Applicant's amended claims fully distinguish over Wang, and Morita fails to cure the above-noted deficiencies of Wang. As noted above, the envisioned combination of references fails to disclose or suggest a pharmaceutical composition consisting essentially of a therapeutically effective amount of a biologically active N-terminal fragment of parathyroid hormone, a pharmaceutically acceptable bulking agent and optionally, an aerosol propellant, **and resulting in the claimed serum profile.**

In view of the above, Applicant respectfully requests that this ground of rejection be withdrawn.

In the prior Action, claim 66 was objected to as depending from an independent claim, which was itself rejected. Applicant had rewritten claim 66 in independent form, incorporating the limitations of the independent claim from which it previously depended. In the present action, claim 66 was rejected only under 5 U.S.C. §112, which rejection applicant contends is overcome by the amendment thereto. Applicant therefore solicits allowance of this claim.

Conclusion

In view of the foregoing, Applicant submits that pending claims 56-57, and 60-68 satisfy the requirements of patentability and are therefore in condition for allowance. Reconsideration and withdrawal of all rejections is respectfully requested and a prompt mailing of a Notice of Allowance is earnestly solicited.

Please grant any extensions of time required to enter this response and charge any additional required fees to deposit account 50-0348.

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If a telephone conference would expedite the prosecution of the subject application,
the Examiner is requested to call the undersigned at (650) 283-6790.

Respectfully submitted,
Nektar Therapeutics

Date: 11/28/07

By: Michael J. Mazza
Michael J. Mazza
Registration No. 30,775

CORRESPONDENCE ADDRESS:

Customer No. 21968

Nektar Therapeutics
201 Industrial Road
San Carlos, CA 94070
(650) 631-3100 (Telephone)
(650) 620-6395 (Facsimile)